UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,818	01/16/2002	Oscar Jimenez	84167	6032

24628 7590 12/15/2004

WELSH & KATZ, LTD
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,818	HIROMI NAMBU	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,10-15 and 18-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 10-15 and 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear

JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 09/13/04.

Response to Amendment

Applicants have amended claims 1, 5, 10 and 11 to recite catheter that was not previously recited in these claims. Claims 3, 8 and 14-16 were withdrawn form consideration because those claims were directed to non-elected species. Claims 1, 2, 4-7, 9-13 and 17 were examined. Applicants have also added new claims 18-24 directed to guide wire and guide wire was not elected by original presentation. Applicants elected heparin as the active agent. Antibiotic is not the same as heparin and applicants did not indicate that they are equivalent and a search for heparin is not a search for antibiotics. However, the current amendment to the claims directs the invention to catheter and guide wires that are coated with the originally elected composition. Applicants traverse the restriction requirement on the grounds of the current amendment of the claims to catheter. Although, the traversal is not persuasive, the new catheter and guide wire claims are examined together.

Contrary to applicant's statement regarding claims 1-17 in the remarks, claims 3, 8 and 14-16 were not rejected because claims 3, 8 and 14-16 were withdrawn from consideration.

The amendment to the claims gives rise to the rejections below.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 5 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brabander-van den Berg et al. (US 5,998,565) in view of Barry et al. (US 6,663,606).

de Brabander-van den Berg discloses a composition comprising polyamidoamine dendrimers (column 3, lines 5-14) and additives where the additives are polyurethanes or polyvinylpyrrolidone (column 4, lines 31 and 32), dye or antioxidant (column 5, lines 28-61) and polyurethanes (column 6, line 27). Regarding the colloidal nature of the polyurethane, de Brabander-van den Berg does not exclude colloidal polyurethane. de Brabander-van den Berg discloses that polyvinylpyrrolidone is a compound that is used to attach polar groups to the dendrimer. The ability of the instant composition 1 to load an active agent is a property of the composition and would be inherent to the composition of the prior art.

de Brabander-van den Berg discloses the instant composition but is silent on using the instant composition to coat a catheter or guide wire, where a guide wire is a form of catheter. But Barry discloses treating the surface of catheter (column 5, line 5) with heparin (column 6, line 66) or polyvinylpyrrolidone (column 6, line 67) or polyamidoamine dendrimers (column 7, line 2). This disclosure indicates that polyamidoamine dendrimer, polyvinylpyrrolidone and heparin have equivalent efficacy in preventing substantial reduction in the pharmaceutical efficacy of pharmaceutically active material carried by the catheter; Barry's disclosure also indicates the state of the art that catheters (and guide wire as a form of catheter) can be coated and in Barry with composition containing dendrimer or heparin or polyvinylpyrrolidone.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a catheter that is coated with composition comprising polyamidoamine dendrimers, polyurethanes, polyvinylpyrrolidone, dye or antioxidant. One

having ordinary skill in the art would have been motivated to coat the catheter or guide wire with the composition comprising polyamidoamine dendrimers, poly-urethanes, polyvinylpyrrolidone, dye or antioxidant with the expectation of preventing substantial reduction in the pharmaceutical efficacy of pharmaceutically active material carried by the catheter according to the disclosure of Barry.

3. Claims 1, 5 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froehling et al. (US 6,232,379) in view of Barry et al. (US 6,663,606).

Froehling discloses a composition that comprises a polyamidoamine dendrimer (column 4, line 8), polyurethane or polyvinylpyrrolidone (column 3, lines 29-35) and dyes (column 4, lines 23 and 24). Regarding the colloidal nature of the polyurethane, Froehling does not exclude colloidal polyurethane. The ability of the instant composition 1 to load an active agent is a property of the composition and would be inherent to the composition of the prior art.

Froehling discloses the instant composition but is silent on using the instant composition to coat a catheter or guide wire, where a guide wire is a type of catheter. But Barry discloses treating the surface of catheter (column 5, line 5) with heparin (column 6, line 66) or polyvinylpyrrolidone (column 6, line 67) or polyamidoamine dendrimers (column 7, line 2). This disclosure indicates that polyamidoamine dendrimer, polyvinylpyrrolidone and heparin have equivalent efficacy in preventing substantial reduction in the pharmaceutical efficacy of pharmaceutically active material carried by the catheter; Barry's disclosure also indicates the state of the art that catheters (and guide wire as a form of catheter) can be coated and in Barry with composition containing dendrimer or heparin or polyvinylpyrrolidone.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a catheter that is coated with composition comprising polyamidoamine dendrimers, poly-urethanes, polyvinylpyrrolidone and dye One having ordinary skill in the art would have been motivated to coat the catheter or guide wire with the composition comprising polyamidoamine dendrimers, poly-urethanes, polyvinylpyrrolidone and dye with the expectation of preventing substantial reduction in the pharmaceutical efficacy of pharmaceutically active material carried by the catheter according to the disclosure of Barry.

4. Claims 1, 5, 10-15 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong (US 5,869,127) and Karimi et al. (EP 0 496 305) in view of Barry et al. (US 6,663,606).

Zhong discloses a method of coating a substrate with a continuous bioactive surface coating (abstract); the substrate to be coated can be a catheter (column 3, lines 65) and the bioactive agent heparin or sodium heparin (column 7, lines 49, examples 1 and 8). The coating composition also contains polyurethane; and Zhong discloses coating the substrate by dipping the substrate in the coating compositions followed by air-drying (examples 1 and 8).

Karimi discloses a composition that comprises a mixture of polyvinylpyrrolidone and polyurethane for coating surfaces such as catheter to make the surface lubricious such that when the medical instrument, in this case, catheter is inserted into the patient in need thereof, the lubricious surface contributes to patient comfort (page 2, lines 1-11).

A combined teaching of Zhong and Karimi would be a catheter coated with a composition that comprises polyurethane, polyvinylpyrrolidone and heparin or sodium heparin. However, the combined teaching of Zhong and Karimi failed to teach a composition that

comprises polyurethane, heparin or sodium heparin and dendrimers or dendritic polymers and polyvinylpyrrolidone.

But Barry discloses treating the surface of catheter (column 5, line 5) with heparin (column 6, line 66) or polyvinylpyrrolidone (column 6, line 67) or polyamidoamine dendrimers (column 7, line 2). This disclosure indicates that polyamidoamine dendrimer, polyvinylpyrrolidone and heparin have equivalent efficacy in preventing substantial reduction in the pharmaceutical efficacy of pharmaceutically active material carried by the catheter or guide wire since a guide wire is a form of catheter.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat a catheter with the combined compositions of Zhong and Karimi where the coating composition comprises polyurethane, heparin or sodium heparin and polyvinylpyrrolidone. One having ordinary skill in the art would have been motivated to modify the combined catheter coating composition of Zhong and Karimi by including dendrimer in the composition combined composition with the expectation that the heparin and dendrimer would synergistically prevent reduction in pharmaceutical efficacy of the catheter.

Response to Arguments

Applicants state that de Brabander-van den Berg is not directed to a catheter or a guide wire.

5. Applicants' arguments filed 09/13/04 have been fully considered but they are not persuasive because it is known in the art to coat catheters (see Barry, US 6,663,606) and thus guide wires.

Applicants argue that Froehling does not disclose antibiotics or anti-thrombolitic agents or catheters or guide wires and that Froehling is directed to a process for incorporating active substance in a plastic using dendrimers.

6. Applicants' arguments filed 09/13/04 have been fully considered but they are not persuasive because is it is known in the art to coat catheters (see Barry, US 6,663,606) and thus guide wires. It is also respectfully noted that Froehling does not have to disclose antibiotic or anti-thrombolitic agents because the claims selects the agent from the group consisting essentially of anti-thrombolitic drug, heparin, sodium heparin, antibiotic and dye and the prior art only has to teach one of the agents to be relevant to the claims.

Applicants argue that Karimi does not teach applicants' coating, that Zhong does not use the term lubricious and that Barry does no coat an outer surface of a catheter with a lubricious coating comprising dye, antibiotic or anti-thrombolitic agent.

7. Applicants' arguments filed 09/13/04 have been fully considered but they are not persuasive. The rejection is based on the combination of the references and applicants' argument is based on the individual references. Thus, in response to applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Karimi discloses a composition that comprises a mixture of polyvinylpyrrolidone and polyurethane for coating surfaces such as catheter to make the surface lubricious such that when the medical instrument, in this case, catheter or guide wire, is inserted into the patient in need

thereof, the lubricious surface contributes to patient comfort. Thus a lubricous coating is disclosed in the prior art. Also, lubricious is a property of a composition and the prior art only has to disclose the composition and the disclosed composition would be lubricious since the property of a composition cannot be separated from the composition. Barry is relied upon a teaching in the art for coating catheter with dendrimer and thus of guide wire and coating the outer surface of the catheter would contribute to patient comfort according to Karimi.

Claim Rejections - 35 USC § 112

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 5, 10-13 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 18 are improper Markush. The Markush recitation should be selected from the group consisting essentially of, and end with an and not wit or as is in the claims 1 and 18.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BF

Blessing Fubara
Patent Examiner
Tech. Center 1600

James M. Spear

JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615